MOVING INTO THE FUTURE WITH ACE/ITDS

2013- 2016

Customs and Border Protection
Modernization
New World, New Tools

TODAY'S OBJECTIVE

- To provide an overview and update of the transition from our current process to the future state

- To provide a high level background on the IWS (Interoperability Web Service) interface to ACE/ITDS (*Automated Commercial Environment/International Trade Data System)*

REASON FOR CHANGE: LEGISLATIVE MANDATE

SAFE PORT ACT – "Single-Window"

The Security and Accountability for Every Port Act, Public Law 109-347 of 2006 … mandates that all Federal agencies, which require documentation for clearing or licensing the importation and exportation of cargo, to participate in ACE/ITDS (Automated Commercial Environment / International Trade Data System).

- **ACE/ITDS deployment of new cargo release functionality by CBP … requires FDA connection… by July 1, 2015.**

- **CBP will mandate that the trade community and Participating Government Agencies (PGAs) use ACE/ITDS earlier than December 2015.**

Characteristics of Interface with CBP

Current Interface

- The Filer/Broker enters the data into the CBP system (ACS). Data in a Flat File format is transmitted through a data line to FDA (OASIS)
- No validation occurs as to whether required FDA data elements exist in the file before sending it to the FDA.
- Every 5 minutes the FDA checks the Gateway between CBP and FDA for the entry/line information;
- If any of the 4 mandatory fields are missing the entry stays in a pending state until the information is updated.

Future Interface

- Filer/Broker enters the data into ACE, CBP **WILL** validate whether required FDA data elements exist in the XML file. If the required elements are not entered, The entry is not transmitted to FDA and the Filer receives a message identifying what information is missing.
- The FDA will receive the information as data allowing for automatic look-ups and validation.
- Detailed messages from the FDA are transmitted to CBP and then to the Filer. Leading to quicker decisions and increased productivity.

Comparison of Data Inputs

Current State

- Filers must provide identical data to different agencies.
- Redundant data may have multiple formats based on agency needs and formats.
- Messages to Industry Regarding Data Lack Details on Missing or Invalid Data.

Future State

- Standardized “Data Formats.”
- Trade Provides Cargo Data One Time and Data are then Transmitted To Multiple Agencies by CBP.
- Real Time Data To FDA/PGAs For Processing.
- Electronic Communications.
- AofCs screening will streamed as digitized to enhance process.

FDA Basics

- FDA Currently Relies upon Electronic Submission of Entry Data.
- FDA is Responsible for Regulating $0.25 of Every Dollar Spent.
- FY 2014 there were approximately 32,600,000 lines submitted with the greatest number of lines associated with CDRH, CFSAN, and CDER.

FDA Product Codes

FDA Product Codes By Center

- CDRH - 3,862
- CTP - 40
- CFSAN - 7,013
- CVM - 554
- CDER - 3,562
- CBER - 157
- CFSAN - 7,013
- Total - 15,188

FDA Supporting Documents

- **Supplemental Guide (Word version)**

Record Identifier PG06 (Product Origin)

This is a conditional PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin, in addition to Processing dates, Processing Type and Processing Description. This record may be used in conjunction with the PG05 to describe the relationship between the genus/species and country of origin, as necessary.

For the Lacey Act, the filer must submit a corresponding genus/species (PG05/PG06) for each Country of Harvest.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 (Country of Refusal) is MANDATORY if previously refused. There would be one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	
Country Code	2X	8-9	M	FDA requires the location of manufacture for all Biologics.	1

- **Supplemental Guide (Excel spreadsheet version)**

						Food/ Feed	Drugs	Devices	Rad Devices	Biologics	Tobacco	Vet Meds	Cosmetics
Record ID	**Data Element**	**Length/ Class**	**Position**	**Status**	**Field Type**	**Required**	**Required**	**Required**	**Required**	**Required**	**Required**	**Required**	**Required**
PG06	Control Identifier	2A	1-2	M	fixed	M	M	M	M	M	M	M	M
PG06	Record Type	2N	3-4	M	fixed	M	M	M	M	M	M	M	M
PG06	Source Type Code	3AN	5-7	M	code	M	M	M	M	M	M	M	M
PG06	Country Code	2X	8-9	M	code	M	M	M	M	M	M	M	M

ACCOMPLISHMENTS TO DATE